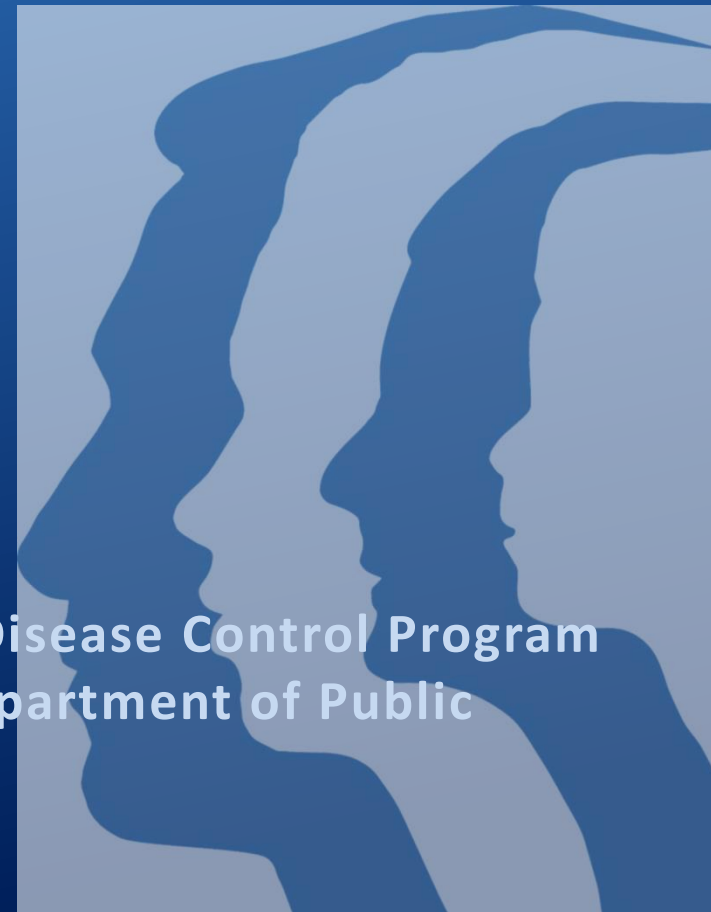


# COVID-19 Vaccine Introduction

December 17th, 2020

**Dr. Naman Shah**

**Acute Communicable Disease Control Program  
Los Angeles County Department of Public  
Health**



## Disclosures

There is no commercial support for today's webinar

Neither the speakers nor planners for today's webinar have disclosed any financial interests related to the content of the meeting

This webinar is meant for healthcare facilities and is off the record and reporters should log off now.

## Disclaimer

- This is a rapidly evolving situation so the information being presented is current as of today (12/17/20) so we highly recommend that if you have questions after today you utilize the resources that we will review at the end of this presentation.

# Objectives

1. Understand the biology and development of COVID-19 vaccines
2. Understand the importance of COVID-19 vaccination, particularly for healthcare workers
3. Discuss updates on COVID-19 vaccine roll-out for LA County



# **1. COVID-19 Vaccine: Development, mechanism, safety**





# LA County Epidemiology Update

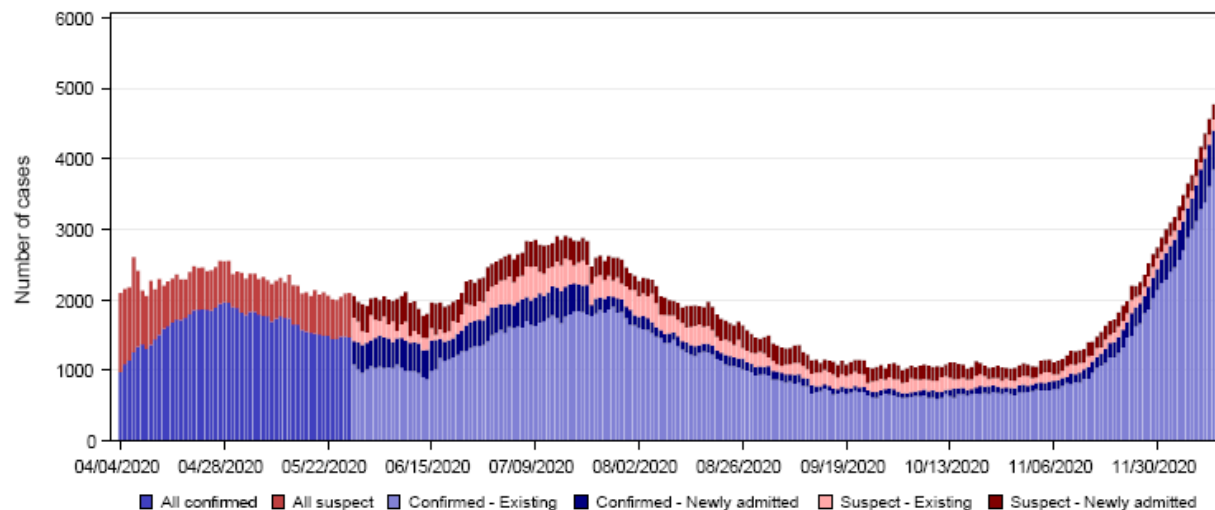
## Los Angeles County Hospitalized Patients Report

Date Reported: 12/15/2020

92 Hospitals Reporting

Number of hospitalized confirmed COVID patients	Number of hospitalized suspect COVID patients	Total confirmed and suspect hospitalized COVID patients	Difference in confirmed case count from yesterday	Percent change in confirmed case count from prior day	Number of confirmed patients newly admitted	Number of suspect patients newly admitted	Number of confirmed cases currently in ICU	Percent of confirmed COVID patients currently in ICU	Number of confirmed and suspected COVID patients currently ventilated	Percent of confirmed and suspected COVID patients currently ventilated
4864	344	5208	208	4.5%	654	218	991	20%	740	14%

Number of confirmed and suspect cases



# COVID-19 vaccine results

- A scientific, collaborative triumph with better and faster results than expected:

94% efficacious

- Endpoint was symptomatic disease. Also reduced severe COVID-19 by 90-100%.
- Reassuringly similar results from two largely similar vaccines
- Extensively studied with 43,000+ (Pfizer) and 30,000+ (Moderna) phase 3 participants
- Wide ages and 42% and 37% respectively from diverse racial and ethnic groups
- 25% >65-year-old, 25% comorbidity

NEWS / Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study

## PFIZER AND BIONTECH ANNOUNCE VACCINE CANDIDATE AGAINST COVID-19 ACHIEVED SUCCESS IN FIRST INTERIM ANALYSIS FROM PHASE 3 STUDY

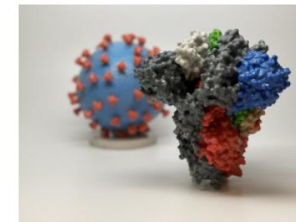
Monday, November 09, 2020 - 06:45am

- Vaccine candidate was found to be more than 90% effective in preventing COVID-19 in participants without evidence of prior SARS-CoV-2 infection in the first interim efficacy analysis
- Analysis evaluated 94 confirmed cases of COVID-19 in trial participants
- Study enrolled 43,538 participants, with 42% having diverse backgrounds, and no serious safety concerns have been observed; Safety and additional efficacy data continue to be collected
- Submission for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) planned for soon after the required safety milestone is achieved, which is

Monday, November 16, 2020

## Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine

An independent data and safety monitoring board (DSMB) overseeing the Phase 3 trial of the investigational COVID-19 vaccine known as mRNA-1273 reviewed trial data and shared its interim analysis with the trial oversight group on Nov. 15, 2020. This interim review of the data suggests that the vaccine is safe and effective at preventing symptomatic COVID-19 in adults. The interim analysis comprised 95 cases of symptomatic COVID-19 among volunteers. The DSMB reported that the candidate was safe and well-tolerated and noted a vaccine efficacy rate of 94.5%. The findings are statistically significant, meaning they are likely not due to chance. 90 of the cases occurred in the placebo group and 5 occurred in the vaccinated group. There were 11 cases of severe COVID-19 out of the 95 total, all of which occurred in the placebo group.



3D print of a spike protein of SARS-CoV-2, the virus that causes COVID-19. In front of a 3D print of a SARS-CoV-2 spike protein.

### Institute/Center

National Institute of Allergy and Infectious Diseases (NIAID)

### Contact

NIAID Office of Communications  
301-402-1663

### Connect with Us

- ☒ Subscribe to news releases
- ☐ RSS Feed

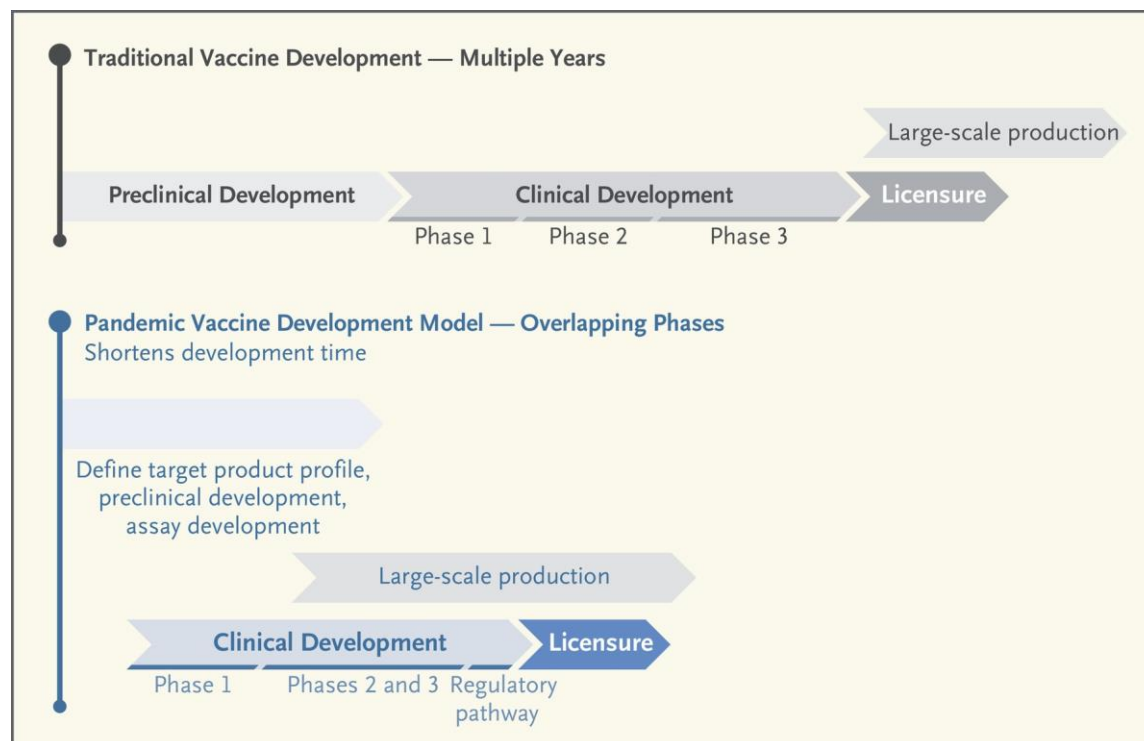
# Sub-group efficacy analysis

- Age, race, sex, co-morbidity subgroups analyzed
  - Elderly
  - Various illnesses: obesity, DM2, HTN, CKD, Liver disease, Cancer, more
  - Not powered for these, similar efficacy for all (not statistically different)
- Partial immunization efficacy (after 1<sup>st</sup> dose alone):
  - ~60-90%
  - Vaccinate as soon as possible



# COVID-19 vaccine development

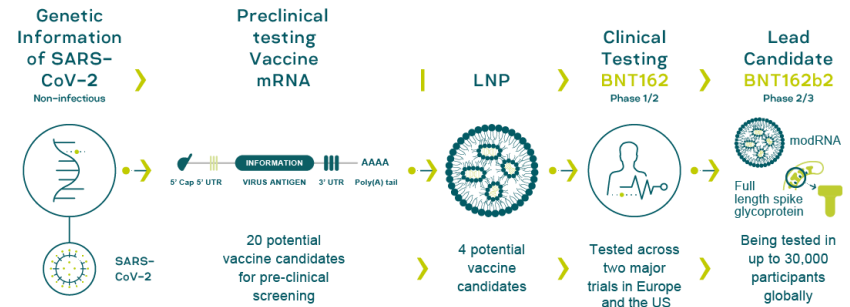
- Jump started thanks to lessons from vaccine development since 2003 with SARS-CoV then MERS coronaviruses
- No skipped steps: Phases 1, 2, 3 completed
- Timeline shortened by overlapping certain phases including manufacturing
- 2 months of full safety data available for EUA



# Mechanism of Action

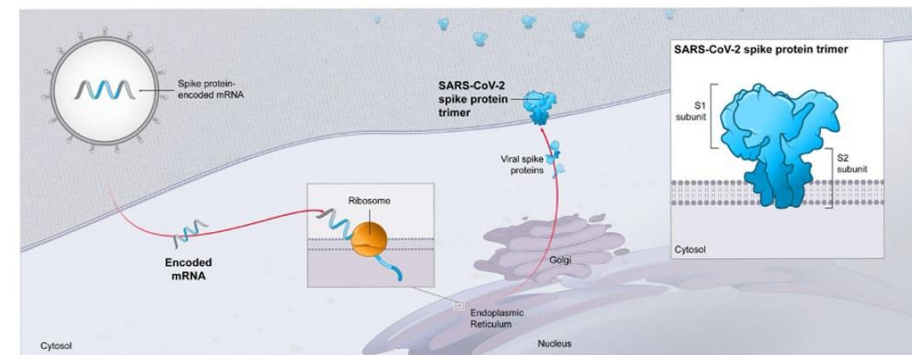
- mRNA codes for the viral spike (S) protein which is used to enter human cells through the ACE2 receptor
- Encapsulated in lipid nano-particles that stabilize and allow cell entry
- Translated by ribosomes with the spike protein then anchored on the cell wall
- Recognized by antigen presenting cells leading to the development of humoral (antibody) and cellular immunity
- Does NOT affect our DNA

## Our mRNA-based approach for a COVID-19 vaccine



BioNTech

## mRNA-1273 encodes for the full-length Spike Protein in the Pre-fusion Conformation (S-2P)



Moderna

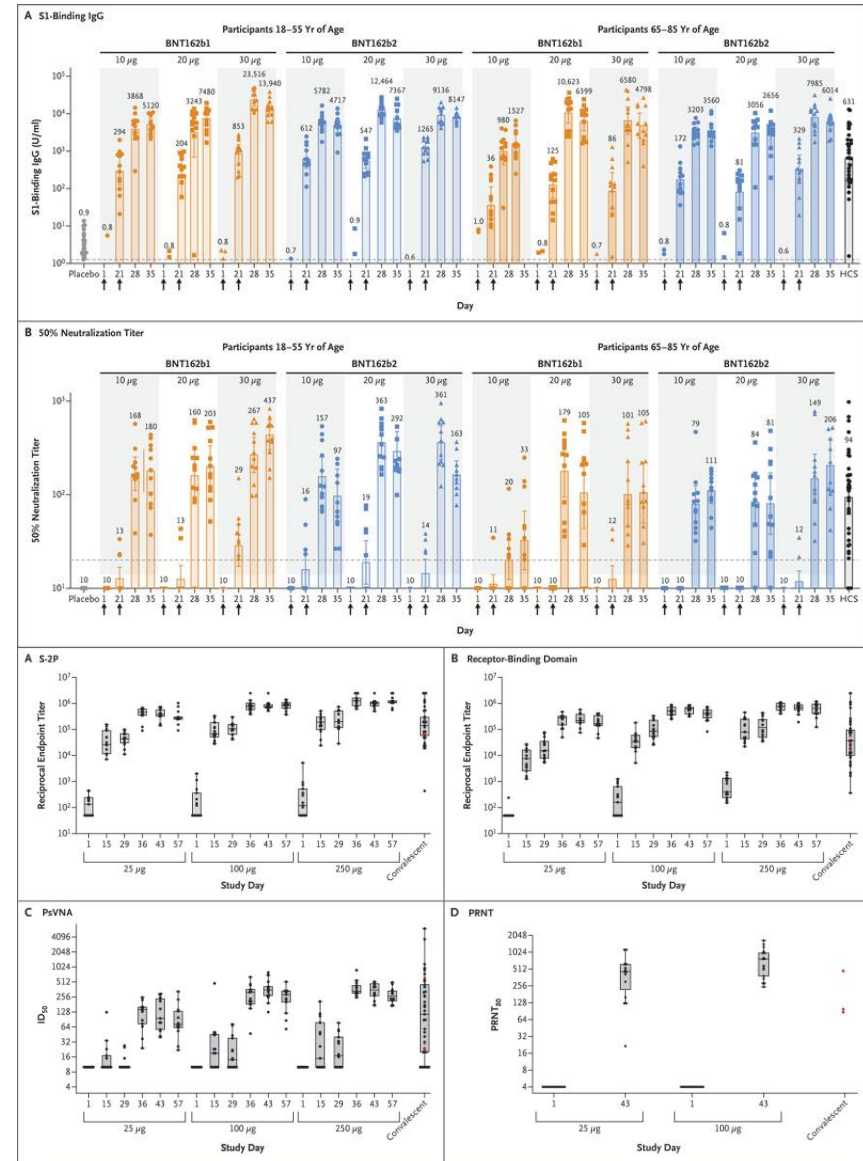
# Immune response data

Phase 2 immune correlates studied:

- Antibody titers
- Virus neutralization
- T-cell responses (Moderna)
- Compared against convalescent serum (natural infection)
- Summary:
  - Robust responses in all three measures
  - Notably, higher than achieved by natural infection in plasma donors
- Corresponds with phase 3 clinical correlation, but unclear implications for duration of protection, and benefit to those with prior infection

Pfizer

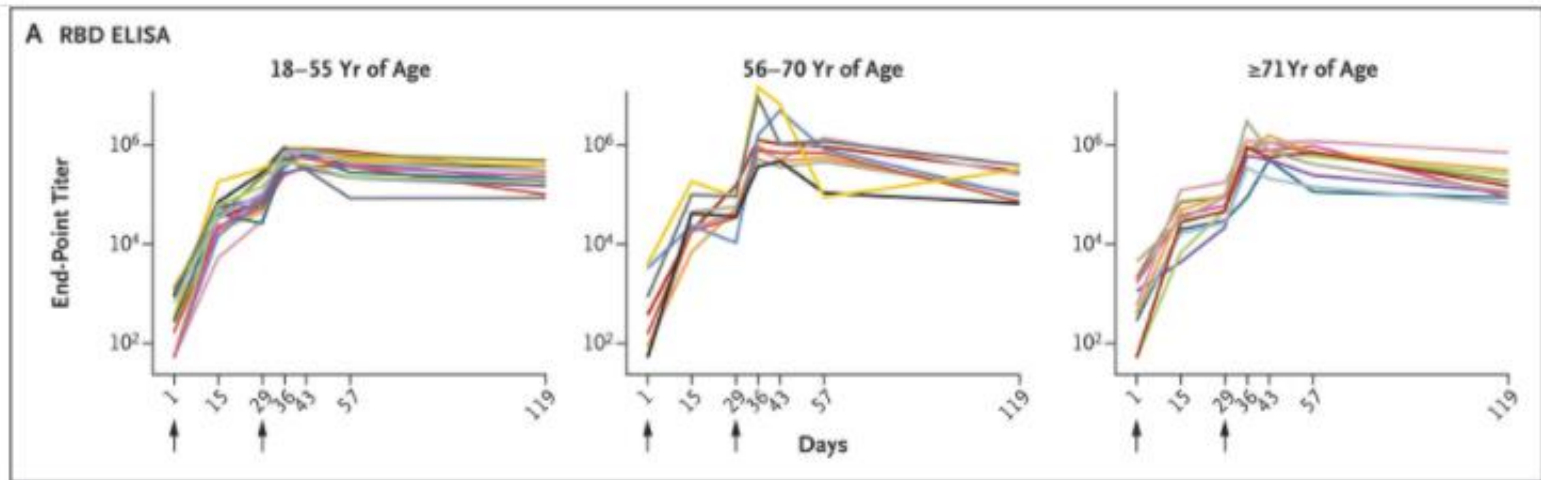
Walsh  
NEJM  
2020



Moderna

Jackson  
NEJM  
2020

# Antibody titers over time



Widge et al. NEJM 2020

- Stable over 4 months so far

# Brief review

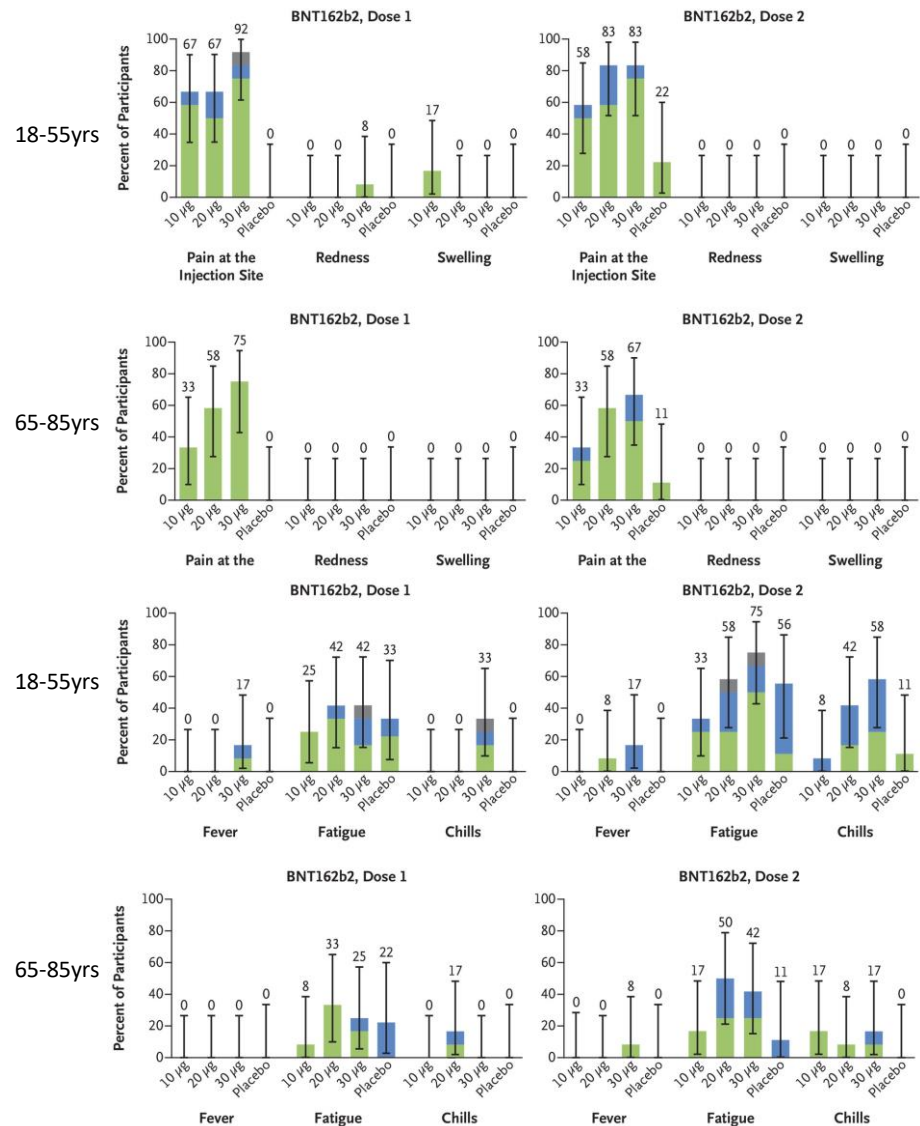
Vaccine	Preparation	Route	Dosing	Storage		Ages	Contraindications
Pfizer/ BioNTech	30µg in 0.3mL  5 dose vial	IM	2 doses  21d apart	-80°C	6m	>16	Severe allergy to vaccine component Precaution: any other injectable med or vaccine
				4°C	5d		
				Room	6h		
Moderna	100µg in 0.5mL  10 dose vial	IM	2 doses  28d apart	-20°C	6m	>18	EUA pending
				4°C	30d		
				Room	12/6h		

# Safety data: Pfizer

- In >43,000 phase 3 participants:  
No serious adverse events reported  
No evidence of antibody-dependent enhancement

## Phase 3 detailed data

- Local events:  
Mostly mild, pain at site of injection was common
- Systemic events:  
Mostly mild, fatigue was common
- Summary:  
Mild reactions, more after the 2<sup>nd</sup> dose





# Safety Data: Unsolicited Adverse Events

**Table 19. Frequency of Unsolicited AEs with Occurrence in  $\geq 1\%$  of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population\*, 16 Years of Age and Older**

<b>System Organ Class Preferred Term</b>	<b>BNT162b2 N=18801 n (%)</b>	<b>Placebo N=18785 n (%)</b>	<b>Total N=37586 n (%)</b>
General disorders and administration site conditions	3521 (18.7)	737 (3.9)	4258 (11.3)
Injection site pain	2125 (11.3)	286 (1.5)	2411 (6.4)
Fatigue	1029 (5.5)	260 (1.4)	1289 (3.4)
Pyrexia	1146 (6.1)	61 (0.3)	1207 (3.2)
Chills	999 (5.3)	87 (0.5)	1086 (2.9)
Pain	455 (2.4)	36 (0.2)	491 (1.3)
Musculoskeletal and connective tissue disorders	1387 (7.4)	401 (2.1)	1788 (4.8)
Myalgia	909 (4.8)	126 (0.7)	1035 (2.8)
Arthralgia	212 (1.1)	82 (0.4)	294 (0.8)
Nervous system disorders	1158 (6.2)	460 (2.4)	1618 (4.3)
Headache	973 (5.2)	304 (1.6)	1277 (3.4)
Gastrointestinal disorders	565 (3.0)	368 (2.0)	933 (2.5)
Diarrhoea	194 (1.0)	149 (0.8)	343 (0.9)
Nausea	216 (1.1)	63 (0.3)	279 (0.7)

Source: FDA analysis.

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

%: n/N. n = number of participants reporting at least 1 occurrence of the specified event.

of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

\* Participants  $\geq 16$  years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

# Safety data: solicited AEs (systemic), 18-55

- Median onset
  - 1-2 days after either dose
- Median duration
  - 1 day after either dose
- Mild, moderate, severe

**Table 17. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Vaccination-Reactogenicity Subset of the Phase 2/3 Safety Population\*, 18 to 55 Years of Age**

Adverse Event	BNT162b2 Dose 1 N=2238 n (%)	Placebo Dose 1 N=2248 n (%)	BNT162b2 Dose 2 N=2045 n (%)	Placebo Dose 2 N=2053 n (%)
<b>Fever</b>				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
>38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
<b>Fatigue<sup>a</sup></b>				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	46 (2.0)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
<b>Headache<sup>a</sup></b>				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
<b>Chills<sup>a</sup></b>				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
<b>Vomiting<sup>b</sup></b>				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
<b>Diarrhea<sup>c</sup></b>				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
<b>* New or worsened joint pain<sup>a</sup></b>				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
<b>Use of antipyretic or pain medication</b>	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Source: adapted from EUA 27036, amendment 3, Table 19.

n = number of participants with the specified reaction.

N = number of participants in the reactogenicity subset reporting at least 1 yes or no response for the specified reaction after the specified dose.

<sup>a</sup> Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.

<sup>b</sup> Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.

<sup>c</sup> Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.

\* Participants in the reactogenicity subset of the safety population ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.



## Other AE points

- Among unsolicited non-serious AE, transient lymphadenopathy was vaccine associated
  - <0.5%
- No serious AEs were vaccine associated
- Unsolicited AE within 30 mins 0.3-0.4% (same as placebo)
- Hypersensitivity related AE 0.6% (similar to placebo 0.5%)

# Special populations

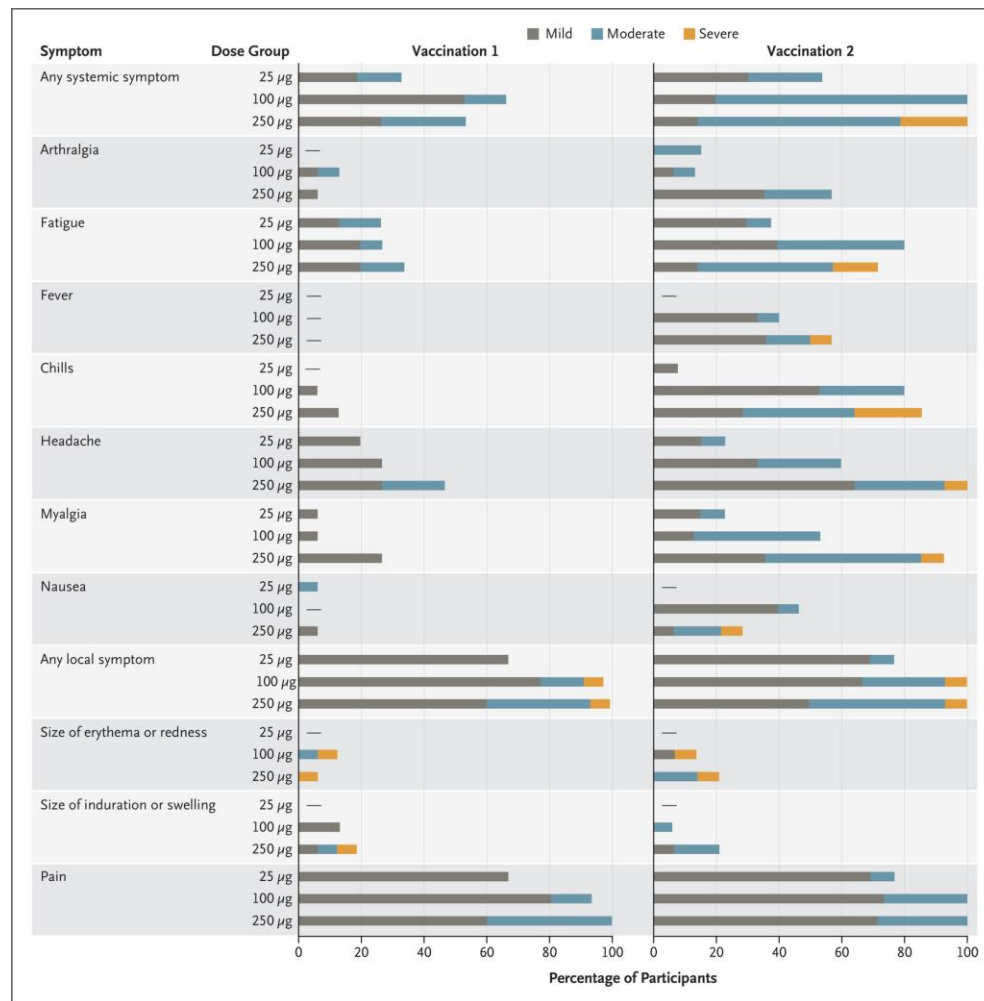
- Pregnancy
  - 23 pregnancies (12 vaccine, 11 placebo)
  - Unsolicited AEs include spontaneous abortion and retained POCs (placebo)
- Immunocompromised
  - Data are insufficient for assessing safety
  - Narrow definition of immunocompromised
- Prior SARS-CoV-2, n=1,093
  - Data are insufficient for benefit
  - No safety concerns noted

# Safety data: Moderna

- In >30,000 phase 3 participants:
  - No serious adverse events reported
  - No evidence of antibody-dependent enhancement

## Phase 3 detailed data

- Local events:
  - Mostly mild, pain at site of injection was common
- Systemic events:
  - Mostly mild, fatigue and headache were common with chills, fever, and myalgia presenting after the 2<sup>nd</sup> dose
- Summary:
  - Mild to moderate reactions, more after the 2<sup>nd</sup> dose



# Safety Data: Unsolicited Adverse Events (real-world)

**Table 26. Unsolicited Adverse Events Occurring in  $\geq 1\%$  of Vaccine Group Participants, by MedDRA Primary System Organ Class and Preferred Term (Safety Analysis Set)<sup>a</sup>**

System Organ Class Preferred Term	Vaccine N=15184 n (%)	Vaccine N=15184 n (%)	Placebo N=15165 n (%)	Placebo N=15165 n (%)
	Any	Severe	Any	Severe
Infections and infestations	521 (3.4)	13 (<0.1)	621 (4.1)	25 (0.2)
Vascular disorders	149 (1.0)	28 (0.2)	138 (0.9)	39 (0.3)
Nervous system disorders	624 (4.1)	27 (0.2)	552 (3.6)	21 (0.1)
Headache	435 (2.9)	19 (0.1)	409 (2.7)	13 (<0.1)
Respiratory, thoracic and mediastinal disorders	480 (3.2)	8 (<0.1)	522 (3.4)	9 (<0.1)
Cough	148 (1.0)	1 (<0.1)	143 (0.9)	1 (<0.1)
Oropharyngeal pain	137 (0.9)	1 (<0.1)	184 (1.2)	3 (<0.1)
Gastrointestinal disorders	426 (2.8)	14 (<0.1)	387 (2.6)	16 (0.1)
Diarrhea	178 (1.2)	2 (<0.1)	147 (1.0)	1 (<0.1)
Skin and subcutaneous tissue disorders	213 (1.4)	4 (<0.1)	158 (1.0)	2 (<0.1)
Musculoskeletal and connective tissue disorders	586 (3.9)	24 (0.2)	521 (3.4)	18 (0.1)
Arthralgia	174 (1.1)	10 (<0.1)	152 (1.0)	2 (<0.1)
Myalgia	172 (1.1)	11 (<0.1)	138 (0.9)	0
General disorders and administration site	894 (5.9)	43 (0.3)	560 (3.7)	13 (<0.1)
Fatigue	344 (2.3)	12 (<0.1)	307 (2.0)	7 (<0.1)
Injection site pain	147 (1.0)	6 (<0.1)	49 (0.3)	1 (<0.1)
Injury, poisoning and procedural complications	238 (1.6)	16 (0.1)	262 (1.7)	13 (<0.1)

Source: Sponsor's Tables 14.3.1.8.1 and 14.3.1.17.1

n (%)=number (percentage) of participants reporting the adverse event at least once

<sup>a</sup> EUA request (interim analysis): November 11, 2020 data cutoff.

## Safety data: solicited AEs (systemic)

- Median onset
  - 1-2 days after either dose
- Median duration
  - 2 days after either dose
- Few grade 3 (severe; preventing daily activity or took medicine) or 4 (ER or hospitalization)
- Fewer in elderly
- More after 2<sup>nd</sup> dose

**Table 23. Frequency of Solicited Systemic Adverse Reactions Within 7 Days Following Either the First or Second Dose of Vaccine, Participants Age 18-64 years, Solicited Safety Set<sup>a</sup>**

Adverse Reaction	Vaccine Group Dose 1 n/N (%)	Placebo Group Dose 1 n/N (%)	Vaccine Group Dose 2 n/N (%)	Placebo Group Dose 2 n/N (%)
Any Systemic	6503/11405 (57.0)	5063/11406 (44.4)	8484/10358 (81.9)	3967/10320 (38.4)
Grade 3	363/11405 (3.2)	248/11406 (2.2)	1801/10358 (17.4)	215/10320 (2.1)
Grade 4	5/11405 ( $<0.1$ )	4/11406 ( $<0.1$ )	10/10358 ( $<0.1$ )	2/10320 ( $<0.1$ )
Fever	105/11403 (0.9)	39/11404 (0.3)	1806/10352 (17.4)	38/10315 (0.4)
Grade 3	10/11403 ( $<0.1$ )	1/11404 ( $<0.1$ )	168/10352 (1.6)	1/10315 ( $<0.1$ )
Grade 4	4/11403 ( $<0.1$ )	4/11404 ( $<0.1$ )	10/10352 ( $<0.1$ )	2/10315 ( $<0.1$ )
Headache	4031/11401 (35.4)	3303/11404 (29.0)	6500/10357 (62.8)	2617/10317 (25.4)
Grade 3	219/11401 (1.9)	162/11404 (1.4)	515/10357 (5.0)	124/10317 (1.2)
Fatigue	4384/11401 (38.5)	3282/11404 (28.8)	7002/10357 (67.6)	2530/10315 (24.5)
Grade 3	120/11401 (1.1)	83/11404 (0.7)	1099/10357 (10.6)	81/10315 (0.8)
Grade 4	1/11401 ( $<0.1$ )	0	0	0
Myalgia	2698/11401 (23.7)	1626/11404 (14.3)	6353/10357 (6.1)	1312/10316 (12.7)
Grade 3	73/11401 (0.6)	38/11404 (0.3)	1032/10357 (10.0)	39/10316 (0.4)
Arthralgia	1892/11401 (16.6)	1327/11404 (11.6)	4685/10357 (45.2)	1087/10315 (10.5)
Grade 3	47/11401 (0.4)	29/11404 (0.3)	603/10357 (5.8)	36/10315 (0.3)
Grade 4	1/11401 ( $<0.1$ )	0	0	0
Nausea/Vomiting	1069/11401 (9.4)	908/11404 (8.0)	2209/10357 (21.3)	754/10315 (7.3)
Grade 3	6/11401 ( $<0.1$ )	8/11404 ( $<0.1$ )	8/10357 ( $<0.1$ )	8/10315 ( $<0.1$ )
Chills	1051/11401 (9.2)	730/11404 (6.4)	5001/10357 (48.3)	611/10315 (5.9)
Grade 3	17/11401 (0.1)	8/11404 ( $<0.1$ )	151/10357 (1.5)	14/10315 (0.1)

Source: Sponsor's Tables 14.3.1.1.4 and 14.3.1.1.5

<sup>a</sup> EUA request (interim analysis)-November 11 2020

<sup>b</sup>Safety Analyses Set: all randomized participants who received  $\geq 1$  vaccine or control dose.

Note: Adverse reaction data were collected on the electronic diary (e-Diary) by participants and those collected on the eCRF indicated as solicited adverse reactions.

n=# of participants with specified reaction

N = number of exposed participants who submitted any data for the event, percentages are based on n/N a: Fever - Grade 3:  $\geq 39.0$  -  $\leq 40.0^{\circ}\text{C}$  or  $\geq 102.1$  -  $\leq 104.0^{\circ}\text{F}$ ; Grade 4:  $>40.0^{\circ}\text{C}$   $>104.0^{\circ}\text{F}$

b: Headache - Grade 3: Significant; any use of Rx pain reliever or prevents daily activity; Grade 4: Requires E.R. visit or

# Special populations

- Pregnancy
  - 13 pregnancies (6 vaccine, 7 placebo)
  - Unsolicited AEs included spontaneous abortion (placebo)
  - New animal tox report: no effects on female reproduction, fetal/embryonal development, or postnatal developmental
- Immunocompromised
  - HIV n=176
  - Data are insufficient
  - Efficacy more of a question than safety
- Prior SARS-CoV-2, n=675
  - Data are insufficient for benefit
  - No safety concerns noted

## Other AE points

- Among unsolicited non-serious AE, transient lymphadenopathy was vaccine associated
  - 1.1% vaccine recipients compared to 0.63% placebo
- No serious AEs were vaccine associated
  - 1 event of intractable nausea and vomiting
  - 2 resolved facial swellings with dermal fillers (similar to flu vaccine)
  - 3 Bell's palsy in vaccine, 1 placebo, unclear association with onset, other URI
- Unsolicited AE within 30 mins 0.6% vaccine, 0.6% placebo
- Hypersensitivity related AE 1.5% (higher than placebo 1.1%)
  - No anaphylactic or severe hypersensitivity reactions

# Continued safety plans

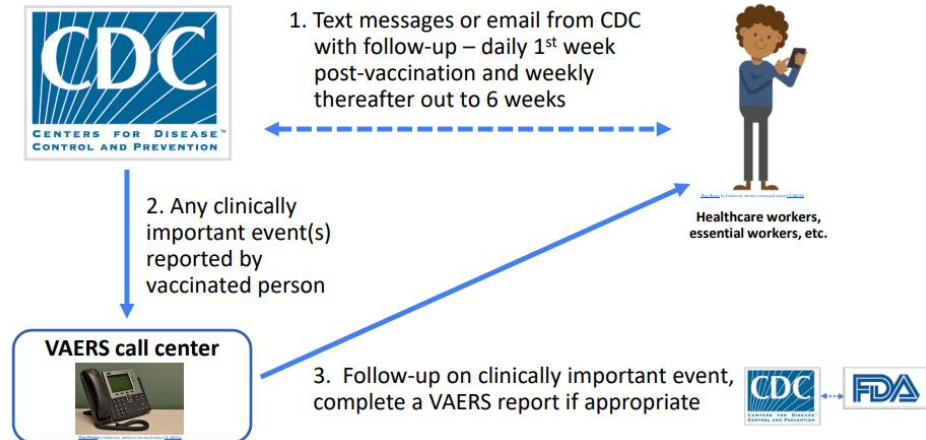
- Total follow-up period of 24 months
- Active and passive data collection
- Continued repeat efficacy and safety analysis among sub-groups
- Pediatric, immunosuppressed, lactation, and pregnancy data needs highlighted



# Reporting Adverse Events

- Mandatory reporting to VAERS :
  - Vaccine administration errors whether associated with an adverse event
  - Serious adverse events (irrespective of attribution to vaccination)
  - Multisystem Inflammatory Syndrome in children and adults
  - Cases of COVID-19 that result in hospitalization or death
- V-safe is a new smartphone-based opt-in program
  - Telephone follow-up to anyone who reports medically important adverse events
  - Missed work, inability to do daily activities, or receiving healthcare triggers VAERS Call Center

## Vaccine safety assessment for essential workers (V-SAFE)



**VAERS**

Vaccine Adverse Event  
Reporting System

Co-managed by  
CDC and FDA

<http://vaers.hhs.gov>



# Recommendation development

- Led by the Advisory Committee on Immunization Practices. ACIP consists of independent medical experts who develop recommendations through regular public meetings
- After FDA EUA approval, ACIP will quickly hold a public meeting to review all available data and review all available clinical trial information, including descriptions of
  - Who is receiving each candidate vaccine (age, race, ethnicity, underlying medical conditions)
  - How different groups respond to the vaccine
  - Side effects experienced
- From these data, ACIP will then vote on whether to recommend the vaccine and, if so, who should receive it.

## ACIP Vaccine Recommendations and Guidelines

Advisory Committee on Immunization Practices (ACIP)

### Vaccine-Specific ACIP Recommendations

- |                                                 |                                                  |
|-------------------------------------------------|--------------------------------------------------|
| • <a href="#">Anthrax</a> UPDATED Jan 2020      | • <a href="#">MMRV</a>                           |
| • <a href="#">BCG</a>                           | • <a href="#">Meningococcal</a> UPDATED Sep 2020 |
| • <a href="#">Cholera</a>                       | • <a href="#">Pneumococcal</a>                   |
| • <a href="#">DTaP/Tdap/Td</a> UPDATED Jan 2020 | • <a href="#">Polio</a>                          |
| • <a href="#">Hepatitis A</a> UPDATED Jul 2020  | • <a href="#">Rabies</a>                         |
| • <a href="#">Hepatitis B</a>                   | • <a href="#">Rotavirus</a>                      |
| • <a href="#">Hib</a>                           | • <a href="#">Smallpox (Vaccinia)</a>            |
| • <a href="#">HPV</a>                           | • <a href="#">Typhoid</a>                        |
| • <a href="#">Influenza</a> UPDATED Aug 2020    | • <a href="#">Varicella (Chickenpox)</a>         |
| • <a href="#">Japanese Encephalitis</a>         | • <a href="#">Yellow Fever</a>                   |

### COVID-19 Vaccination Provider Support



Find enrollment, ordering, reporting, reimbursement, and data resources in support of COVID-19 vaccination.

<https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>



# Contraindication

- History of severe allergic reaction (anaphylaxis) to any of the vaccine components
- Polyethylene glycol (PEG), used to increase half-life in several medications, suspected to be the allergic component



# Precautions

- Individuals with a history of anaphylaxis to any injectable medication or vaccine
- Can receive the vaccine, risk/benefit discussion with HCP
- Longer post-vaccination monitoring

# Post-vaccine monitoring

- 15 minutes routinely
- 30 minutes in those with a history of anaphylaxis / family history of any cause

## Algorithm for the triage of persons presenting for Pfizer-COVID-19 vaccine

	PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	<b>CONDITIONS</b> <ul style="list-style-type: none"> <li>•Immunocompromising conditions</li> <li>•Pregnancy</li> <li>•Lactation</li> </ul> <b>ACTIONS</b> <ul style="list-style-type: none"> <li>•Additional counseling*</li> <li>•15-minute observation period</li> </ul>	<b>CONDITIONS</b> <ul style="list-style-type: none"> <li>•Moderate/severe acute illness</li> </ul> <b>ACTIONS</b> <ul style="list-style-type: none"> <li>•Risk assessment</li> <li>•Potential deferral of vaccination</li> <li>•15-minute observation period if vaccinated</li> </ul>	<b>CONDITIONS</b> <ul style="list-style-type: none"> <li>•None</li> </ul> <b>ACTIONS</b> <ul style="list-style-type: none"> <li>•N/A</li> </ul>
ALLERGIES	<b>ALLERGIES</b> <ul style="list-style-type: none"> <li>•History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>•History of allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>•Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)</li> <li>•Family history of anaphylaxis</li> </ul> <b>ACTIONS</b> <ul style="list-style-type: none"> <li>•15-minute observation period</li> </ul>	<b>ALLERGIES</b> <ul style="list-style-type: none"> <li>•History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine)</li> <li>•History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication</li> </ul> <b>ACTIONS:</b> <ul style="list-style-type: none"> <li>•Risk assessment</li> <li>•Potential deferral of vaccination</li> <li>•30-minute observation period if vaccinated</li> </ul>	<b>ALLERGIES</b> <ul style="list-style-type: none"> <li>•History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine</li> </ul> <b>ACTIONS</b> <ul style="list-style-type: none"> <li>•Do not vaccinate</li> </ul>

# Recommended with risk-benefit discussion

- If otherwise part of a recommended population (e.g. HCP, LTCF resident), unless contraindication, vaccine remains recommended with a risk-benefit discussion with the HCP. Including:
  - Pregnancy / breast-feeding
  - Immunosuppressed, HIV
- Safety data limited (but some) and no theoretical safety concerns but known risks of COVID-19 in these groups
- May not achieve similar immunogenicity and efficacy



## Prior positive SARS-CoV-2 test / mAb

- Vaccine recommended unless active infection, i.e., before end of isolation
- Safety data available, no safety concerns
- May consider delaying until more than 90 days post-infection, given low risk of reinfection within this period, to save scarce vaccine supply (must after mAb)
- Recommend against any SARS-CoV-2 testing, including serology, prior to vaccination
- No other vaccines 2 weeks before or after COVID-19 vaccine dose



## Pre-Vaccination Form for Pfizer-BioNTech COVID-19 Vaccine



### For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name \_\_\_\_\_

Age \_\_\_\_\_

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine? If yes, which vaccine product? <input type="checkbox"/> Pfizer <input type="checkbox"/> Another product _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?			
• Was the severe allergic reaction after receiving a COVID-19 vaccine?			
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?			
4. Do you have a bleeding disorder or are you taking a blood thinner?			
5. Have you received passive antibody therapy as treatment for COVID-19?			





## 2. COVID-19 Vaccine: Importance of COVID-19 vaccination



## Individual benefits to vaccination

- Protect yourself COVID-19 disease
- Decrease the risk of severe disease in case of infection
- Prevent spread to loved ones



LA Mask Print Project

**I won't spread flu  
to my patients  
or my family.**

Even healthy people  
can get the flu, and  
it can be serious.

Everyone 6 months  
and older should  
get a flu vaccine.  
This means you.

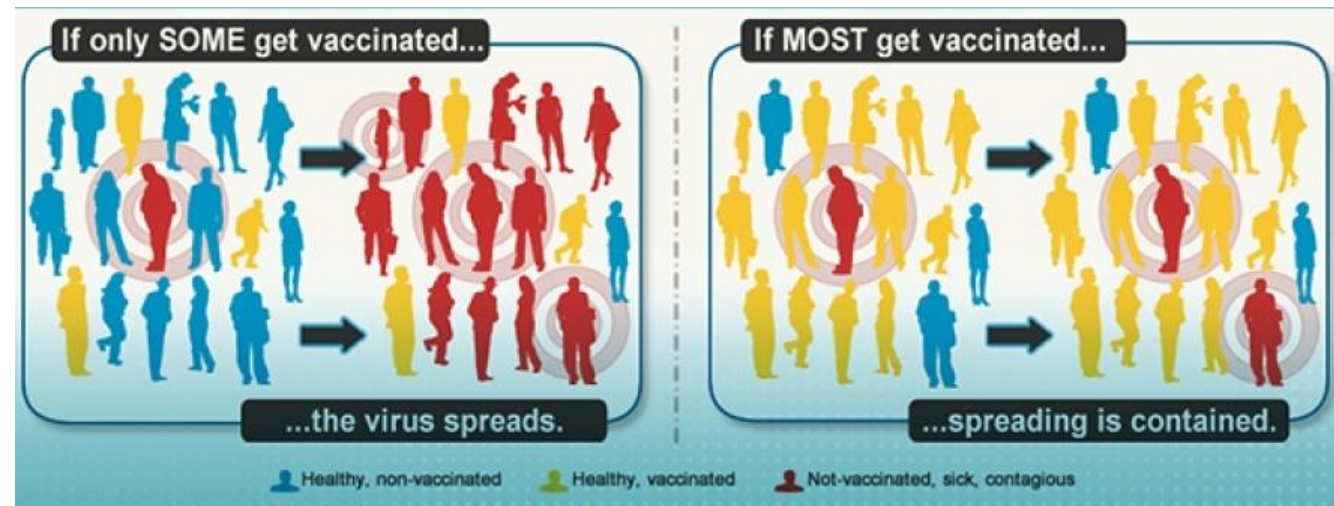
This season, protect  
yourself—and those  
around you—by  
getting a flu vaccine.

For more information, visit: <http://www.cdc.gov/flu>



## Social benefits to vaccination

- Protect others in your community, masking and physical distancing are important but not perfect
- Help maintain essential services and allow economic activity restrictions lifting
- End the pandemic



# Healthcare workers and vaccination

- Priority group number 1 for the limited supplies of the new vaccine because:
  - At higher-risk due to frequent, close exposure
  - Essential workers whose protection is necessary to maintain the functioning of our health system and society
- Healthcare workers are the most trusted source of information on COVID-19 and vaccination for the public.
- Heroes in the eyes of the public for their dedication, and commitment during the pandemic.
- Professional obligation to get vaccinated and continue to lead by example



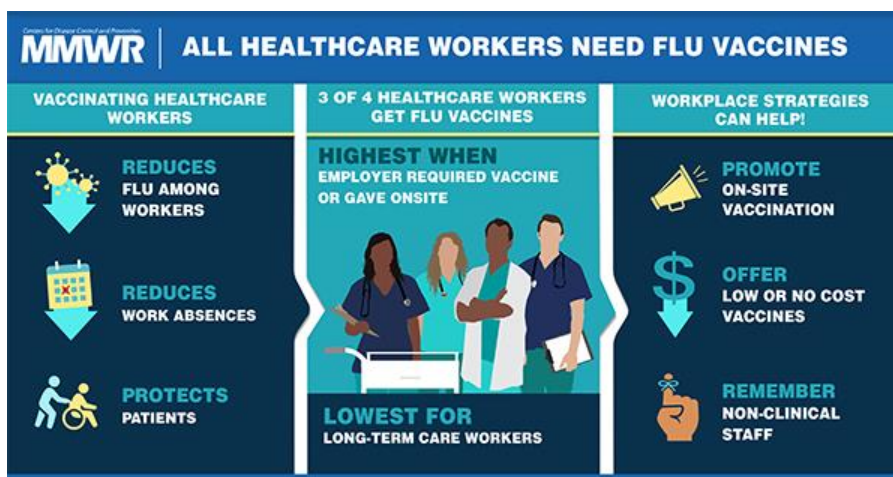
Source: Marvel comics



Source: Banksy

# Improving healthcare worker vaccination

- Use best practices from your experience with flu
- Offer onsite vaccination
- Encourage documentation of refusal to receive including medical and other exemptions
- Mask use required as present for those who decline. Vaccinees also need to mask until data on infection transmission available
- Goals should be the same or higher rate as your previous highest influenza vaccine coverage





### 3. COVID-19 Vaccine: LA County roll-out

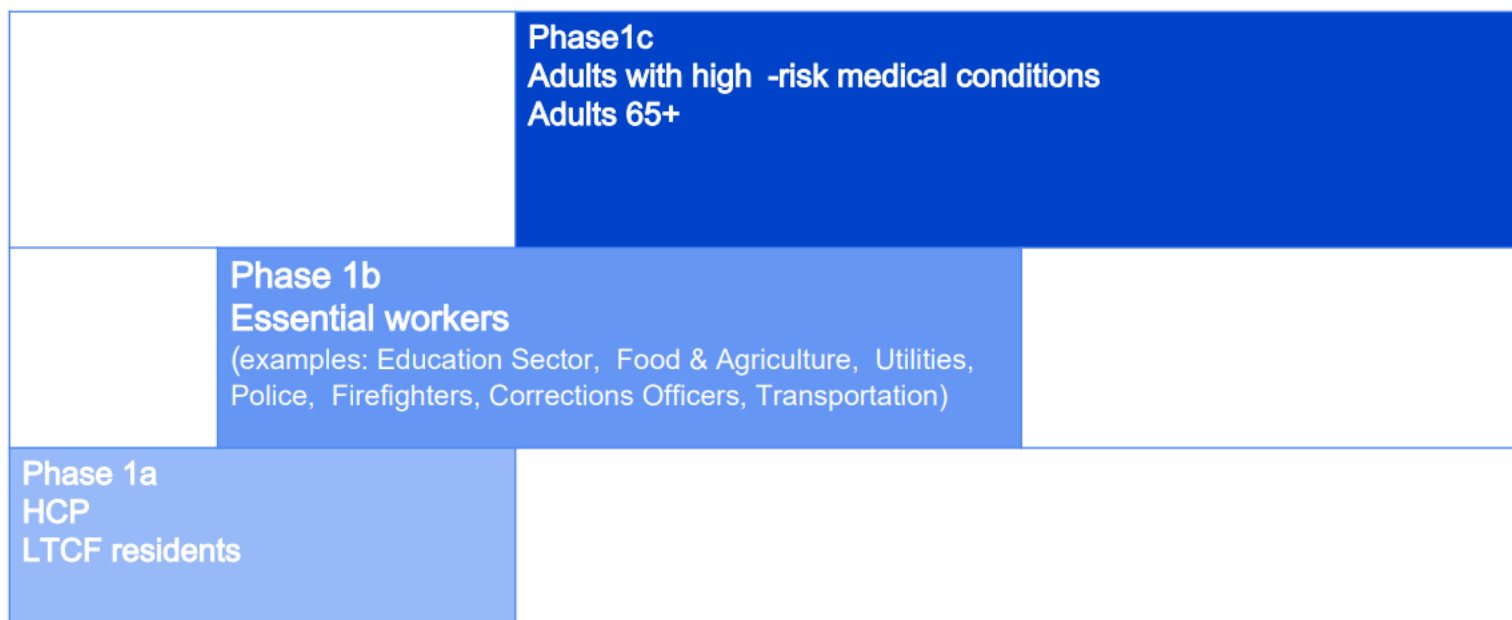






# Phased approach to vaccine availability

## Work Group Proposed Interim Phase 1 Sequence



**Time**



# Consensus values guiding the phases

- Goals for vaccination while supply is limited
  - Decrease death and serious disease as much as possible
  - Preserve functioning of society
  - Reduce the extra burden the disease is having on people already facing disparities
  - Increase the chance for everyone to enjoy health and well-being
- Ethical principles while supply is limited
  - Maximize benefits and minimize harms — Respect and care for people using the best available data to promote public health and minimize death and severe illness
  - Mitigate health inequities — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible
  - Promote justice — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination
  - Promote transparency — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes



# Sources of COVID-19 vaccine supply

- Pre-positioned vaccine:
  - Shipped before EUA so its ready to go once FDA and ACIP approvals made
- Pharmacy partnership for Long-Term Care facilities
- Direct orders
  - Health facilities enrolled in VTrckS through CDPH
- Retail pharmacy program
  - 19 chains and independent as of now
  - 38,000 retail pharmacies covering 60% of the US population



# Vaccine information systems and documentation

- Multiple information needs currently across multiple different systems:
  - Scheduling
  - Ordering
  - Inventory
  - Reporting
- Local and federal reporting requirements
  - Record all individual level vaccine administration in EMR within 24 hours
  - Report all EMR data within 72 hours
- Goal is for an integrated end-to-end system without the need for duplication. May be fragmented initially with progressive improvement.



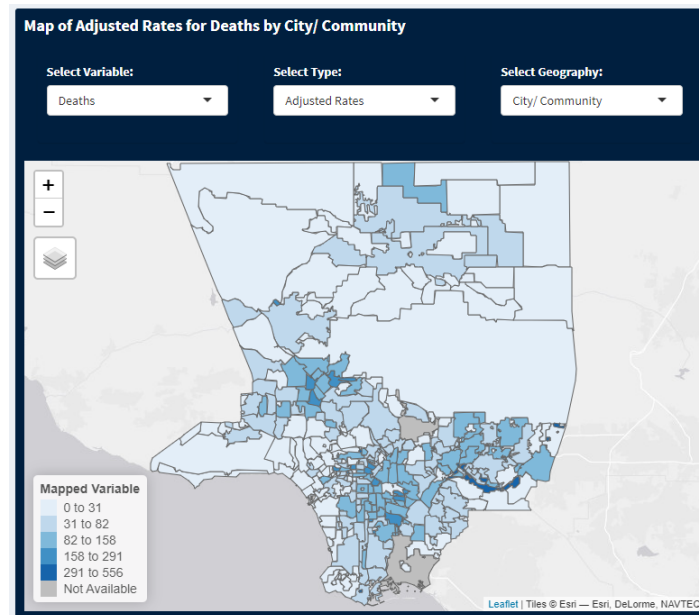
# LA County specifics

- Need for further triaging of the 1A group until large vaccine supplies available
- Planning in process for specifics within facility and between facility
- Informed by data including social vulnerability, healthcare worker surveillance, inputs from many sources
- Health provider outreach
- 82,875 Pfizer doses this week
- ~66,000 Pfizer, 116,000 Moderna next

## COVID-19 Positive Healthcare Workers and First Responders Data, Los Angeles County

Table 2. Occupational Setting of COVID-19 Positive Healthcare Workers and First Responders<sup>1</sup>

Setting	Count	Percent
Skilled Nursing/Assisted Living/Senior Living Facility	5754	32.6%
Hospital	4530	25.7%
Outpatient	1787	10.1%
EMS/First Responder	914	5.2%
Home Health	764	4.3%
Corrections/Detention	709	4.0%
Dental	486	2.8%
Mental Health	457	2.6%
Other Congregate	164	0.9%
Other	156	0.9%
Dialysis	153	0.9%
Pharmacy	137	0.8%
Urgent Care	114	0.6%





# HCW Survey

1. Emphasize vaccine safety and development knowledge, this was least known and impactful. Specifically, Pfizer and Moderna vaccine trial studies involved more than 70,000 participants of all races and ages with no serious adverse events.

2. To encourage vaccine uptake, use targeted messaging on attitudes regarding vaccination, specifically on the importance of the protection of loved ones, protection of patients, and ending the pandemic. These were more important than the vaccines ability to protect oneself.

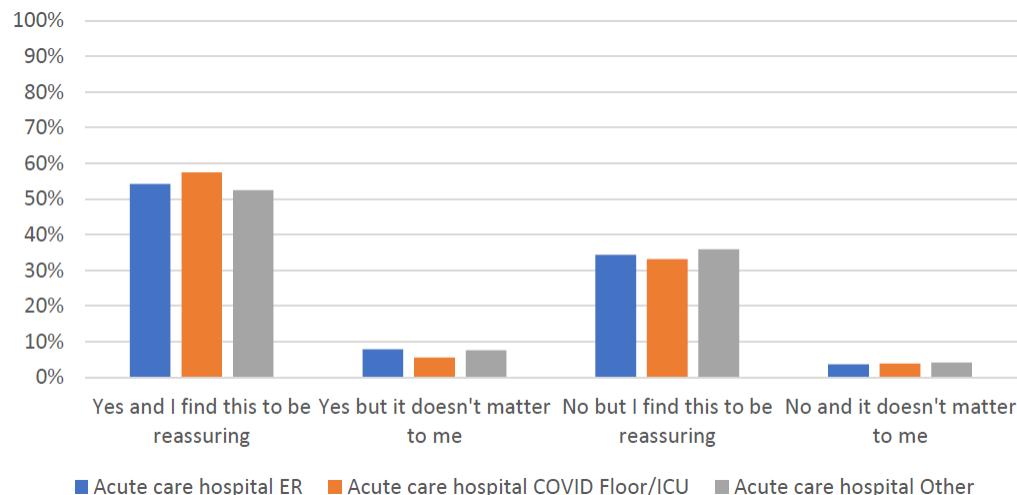
3. Anticipate a rate of 20% signed declinations in acute care hospitals/facilities, varying by staff role based on this sample of healthcare providers.

4. Focus on reaching Nursing staff, to provide them equal opportunity and equal protection as Physicians

5. After news reports from the media, most staff receive their vaccine information through their workplace. You can make a difference by educating and engaging staff with on-site and online vaccination resources!

Do you plan to refuse a recommended COVID-19 vaccine?

	Yes, I will submit a documented exemption	No	Total
Nursing (RN/LVN)	431	1459	1890
	22.8% (*)	77.2% (*)	
Physician/Mid-level	49	1114	1163
	4.21% (*)	95.79% (*)	
Pharmacist	21	136	157
	13.38% (*)	86.62% (*)	
EMT/Paramedic	63	188	251
	25.1% (*)	74.9% (*)	
Certified nursing assistant/medical assistant	66	147	213
	30.99% (*)	69.01% (*)	





# Checklist contents

VACCINE ADMINISTRATION PREPARATION	
<input type="checkbox"/>	Create list of all staff and/or residents who will be vaccinated and register them in <a href="#">PrepMod</a> when creating the clinic/vaccination event.
<input type="checkbox"/>	Create a schedule for staff vaccination including staggering <b>Attachment:</b> <ul style="list-style-type: none"><li>LACDPH Prioritization guidance (Appendix 7)</li></ul>
<input type="checkbox"/>	Develop standing orders/standardized procedures for vaccine administration. <b>Attachment:</b> <ul style="list-style-type: none"><li>Standardized Procedure Template (Appendix 8)</li></ul>

<input type="checkbox"/>	Develop procedure or use internal procedures to obtain assent or consent for staff and/or residents. Every recipient must receive a EUA consent form. Persons receiving the vaccine must assent to vaccination. Consent is neither required nor prohibited.
<input type="checkbox"/>	Create procedure to document declinations for staff <b>Attachment:</b> <ul style="list-style-type: none"><li>COVID Vaccination Declination Template (Appendix 9)</li></ul>
<input type="checkbox"/>	Separate and store PPE and vaccine administration supplies. Ensure additional vaccine administration supplies are available: PPE, sharps containers, alcohol wipes, cotton balls, and additional safety syringes. <b>Attachment:</b> <ul style="list-style-type: none"><li>Product Information Guide – see ancillary supply section (Appendix 15)</li></ul>
	Plan for adverse reactions.  Create return to work and testing protocol  Ensure emergency first aid supplies are sufficient for treating adverse reactions. (i.e.

# Checklist contents

- Appendix included
  - All referenced documents with brief descriptions
- Digital “binder”
  - Zipped file of all the above resources

## COVID – 19 Vaccine Checklist for Health Facilities

### APPENDIX: Supporting Documents Binder

1.	<u>COVIDReadi</u> Provider Enrollment: Before You Enroll – provides guidance on the enrollment process.
2.	<u>COVIDReadi</u> Provider Enrollment Quick Start Guide – provides step by step guidance on how to enroll <u>COVIDReadi</u> .
3.	Guidance on IIS Participation – provides overview of IIS and CAIR requirements and how to enroll.
4.	Guidance on Storage & Handling – review of storage& handling requirements for COVID – 19 vaccines.
5.	Guidance on Temperature Monitoring – review of temperature monitoring requirements.
6.	Refrigerator and Freezer Temp Log – provides guidance on how to document storage temperatures and reporting requirements for out – of – range temperatures.
7.	LACDPH Prioritization Guidance – provides an overview of the department's COVID vaccine allocation plan, including strategies to ensure effective and equitable distribution.
8.	Standardized Procedures for COVID – 19 Vaccination (Template) – this template can be used to create vaccination procedures.
9.	COVID Vaccine Declination – declination form for staff or residents refusing vaccination
10.	Field Operations Guide - provides information, recommendations, and resources to assist in planning for vaccine administration in the field, outside of a controlled clinic setting.
11.	Anaphylaxis Management – provides guidelines for managing an anaphylaxis event.
12.	Preparing Reconstituted Vaccine – provides steps to reconstitute vaccine
13.	COVID – 19 Vaccine Receiving Log – this form should be used to document the number and type of vaccine received.
14.	<u>vSafe</u> – this form provides an overview of the new <u>vSafe</u> program developed by CDC and how to enroll.
15.	Product Information Guide – this guide provides an overview of the COVID vaccines and ancillary supplies that will be shipped with the vaccine.
16.	Reporting Vaccine Inventory in Vaccine Finder – provides step by step guidance on how to register your facility and report COVID vaccine doses in Vaccine Finder.
17.	EZIZ – transporting refrigerated vaccine guide

# Infection prevention and control reminder

- Vaccination for COVID-19 will be critical
- At the same time, for both COVID-19 control, and for other infectious diseases continue public health fundamentals:
  - PPE
  - Staff screening
  - Hand hygiene
  - Precautions
  - Environmental cleaning
  - AMR
  - Routine vaccinations





## Take home points

- Well developed, safe, efficacious vaccines
- Health facility and healthcare worker responsibility
- Patience and understanding with gradual phased roll out





- Is there any vaccine efficacy/safety data for person with co-morbidities?
- Can clinical staff opt out of participating in vaccine administration activities if they believe there is insufficient data on vaccine efficacy/safety in person with co-morbid conditions?
- What is the communication plan to educate the public regarding 2 dose requirement, decreased efficacy with a single dose and the need to continue to use face masks and practice social distancing until vaccine is effective (28 days plus second dose) and until a sufficient number in the population receive 2 doses including time for vaccine to become effective?



Questions?

